REMARKS

Claims 68-77, 79-81, 107, 111, 116-128 and 130-152 are pending. Claims 1-67, 78, 82-106, 108-110, 112-115, 129 and 153-162 are cancelled. Claims 68-77, 79-81, 107, 111, 116-126 and 133-152 have been amended. Claims 68-77, 79-81, 107, 111, 116-126 and 133-152 have been amended for clarity and to fix typographical errors; claims 68, 133 and 143 have been amended to change "binds to an epitope" to "competes for binding to" prostate specific membrane antigen. Claims 153-162, drawn to methods involving antibodies that compete for binding to PSMA, are redundant in light of the amendments, and have been canceled. Support for the amendments can be found, for example, at page 27, lines 26-35 and page 28, lines 6-10, and throughout the application as originally filed. No new matter has been added.

Rejection of Claims 68-77, 79-81, 107, 111, 116-128 and 130-162 Under 35 U.S.C. §112, first paragraph

Claims 68-77, 79-81, 107, 111, 116-128 and 130-162 are rejected under 35 U.S.C. §112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner asserts that the instant disclosure "does not contemplate nor provide a written description of the subgenus of antibodies that specifically recognize the same epitopes and/or competes [*sic.*] with the binding of monoclonal antibodies selected from the group consisting of E99, a J415, a J533, and a J591."

Applicant respectfully traverses this rejection. However, in the interest of expediting prosecution of the present application, the claims have been amended to remove the recitation of antibodies or antigen binding portions thereof that bind to an epitope which is also recognized by a monoclonal antibody selected from the group consisting of E99, a J415, a J533, and a J591. The claims, as amended, are directed to methods involving an antibody or antigen binding portion thereof which competes for binding to prostate specific membrane antigen with a

monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and a J591 monoclonal antibody. The Examiner has also rejected claims containing this language.

The application clearly provides sufficient description of antibodies that compete for binding to PSMA with the recited antibodies such that a skilled artisan would recognize that Applicant was in possession of the claimed invention at the time of filing.

The written description requirement is met if the specification shows that an applicant was in possession of the claimed invention at the time of filing. "When the original specification accomplishes [this], regardless of *how* it accomplishes it, the essential goal of the description requirement is realized." *In re Smith*, 481 F.2d 910, 914 (CCPA 1973). It is well accepted that "in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *ad haec verba* support for the claimed subject matter at issue". *Purdue Pharma v. Faulding, Inc.*, 56 USPQ 2d 1481 (Fed. Cir. 2000); and MPEP § 2163.02. As provided, for example, in *In re Wright*, 866 F.2d 422 (Fed. Cir. 1989), "the fact...that the exact words here in question...are not in the specification is not important" (emphasis added). In *Wright*, the claims at issue involved methods for forming images and included a step of depositing a layer of microcapsules in the form of a free flowing powder. The claims recited that the layer of microcapsules was "not permanently fixed". The Examiner rejected claims with this language, asserting a lack of written description. On appeal, the Federal Circuit held that the original specification unequivocally taught the absence of permanently fixed microcapsules, as demonstrated by a description of the removal of microcapsules from the surface and a warning that the capsules should not be disturbed prior to the formation of the image, and that the written description rejection "was clearly erroneous".

Here, the claimed invention involves a method that uses an antibody having a specific feature: it competes for binding PSMA with a specific, disclosed antibody, namely E99, J591, J415 or J533. The support for this language in the specification of the above-identified application is even clearer than the situation presented in *Wright*. As provided in the Declaration of Abbie Celniker under 37 CFR § 1.132 (hereafter "the Declaration", filed herewith), one of ordinary skill in the art at the time the application was filed would have found that the

specification discloses and that Applicant was in possession of antibodies that compete for binding with one of the specifically disclosed antibodies. Specifically, the Declaration points to page 27 lines 26-35 of the specification of the above-identified application as filed. This passage discusses a particular embodiment wherein antibodies are used to direct two components to a desired site, and provides as follows:

> ***a first biological agent*** is conjugated with a prodrug which is activated only when in close proximity with a prodrug activator. The prodrug activator is conjugated with ***a second biological agent according to the invention, preferably*** one which binds to a non-competing site on the prostate specific membrane antigen molecule. Whether two biological agents bind to competing or non-competing binding sites can be determined by conventional competitive binding assays. (***emphasis added***).

From the passage recited above, it would be clear to one of ordinary skill in the art at the time the application was filed that the cited text, in combination with the rest of the specification, discloses two types of antibodies --those that compete for binding with an antibody "according to the invention" and those that do not compete for binding with an antibody "according to the invention", the later being preferred in the particular embodiment being described. But whether preferred or not, it is clear from the text that Applicant was in possession of the idea of an antibody which competes for binding with an antibody according to the invention. The text also provides, see, e.g., the last sentence of the quoted passage, what constitutes a competing site and a non-competing site by stating that "whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays." Therefore, the application necessarily discloses the concept of an antibody that competes for binding with an antibody according to the invention. Thus, a person of ordinary skill in the art at the time the application was filed would have believed that the concept of having an antibody that competes for binding with "an antibody according to the invention" is necessarily part of the disclosure of the present application and that Applicant was in possession of this element of the invention at the time of filing.

As provided in the Declaration, it is also clear that, upon reviewing the specification of the above-referenced application, one of ordinary skill at the time the application was filed,

would have believed that monoclonal antibodies E99, J415, J533 and J591 are "antibodies according to the invention." These four antibodies are disclosed throughout the application as being antibodies of the invention. In fact, the very next sentence, at page 28, lines 1-6, after the passage recited above states as follows:

> For example, monoclonal antibodies J591, J533, and E99 bind to competing binding sites on the prostate specific membrane antigen molecule. Monoclonal antibody J415, on the other hand, binds to a binding site which is non-competing with the site to which J591, J533, and E99 bind.

Thus, the application necessarily discloses that monoclonal antibodies E99, J415, J533 and J591 are antibodies according to the invention. Given that J415, J591, J533 and E99 are antibodies of the invention, and that the specification clearly supports the concept of antibodies that compete for binding with an antibody of the invention, a skilled artisan would recognize that the application discloses and that Applicant was in possession of antibodies that compete for binding with J415, J591, J533 or E99. The text of the specification describes and shows possession of the claimed subject matter.

For the reasons discussed above, Applicant respectfully requests that the Examiner withdraw this rejection and allow all the currently pending claims.

Enclosed is a Declaration under 37 CFR § 1.132. No fee is believed to be due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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Rolando Medina, Ph.D., J.D.
Reg. No. 54,756

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

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